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| 10/583,033   | 06/15/2006  | Hideki Yoshikawa     | 520.46263X00        | 6757             |
| 20457 7590 12/08/2009<br>ANTONELLI, TERRY, STOUT & KRAUS, LLP<br>1300 NORTH SEVENTEENTH STREET<br>SUITE 1800<br>ARLINGTON, VA 22209-3873 |             |                      |                     |                  |
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| BRUTUS, JOEL F   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,033

**Applicant(s)**

YOSHIKAWA ET AL.

**Examiner**

JOEL F. BRUTUS

**Art Unit**

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-10 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 9/10/2009
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 5-6, 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanda et al (US Pat: 5,910,118) in view of Schwartz et al (US Pat: 5,474,073) and further in view of Robinson (Pub. No.: US 2004/0068188) and/or further in view of Hossack (US Pat: 5,769,079).

Regarding claims 1, 8 and 18, Kanda et al teach a Doppler detector to measure velocity, blood flow and motion that are pertinent to the claimed invention. Kanda et al further teach an ultrasound probe that comprises an array type of piezoelectric transducer arranged at the tip thereof. The transducer has a plurality of piezoelectric elements arranged in an array and arranged in a scanning direction [see column 4 lines 51-59]. Kanda et al also teaches the apparatus comprises means for removing a clutter component; means for extracting information representing a blood flow passing the cross section based on the Doppler signal of which clutter component is removed by the removing means, and means for displaying the extracted information [see column 3 lines 1-10, 55-67]; removing means to subtract a constant value corresponding to the clutter component; estimating means and calculation means [see column 3 lines 5-14].

Kanda et al teaches transmitting an ultrasound signal a plurality of times in each scanning direction composing a cross section to be imaged of an object and receiving an ultrasound echo reflected from along the cross section of the object [see column 3 lines 45-55]. Kanda et al further teaches the echo signal thus extracted then undergoes estimation of motion states of blood flows (including blood flow velocities, power, and dispersion) and two-dimensional tomographic images are produced on the estimated information [see column 2 lines 9-14].

Kanda et uses a moving target indication (MTI) filter that is formed into a high pass filter, a filtering circuit to extract echo signals reflected from blood flow [see column 2 lines 1-9]. Kanda et al also discusses color flow mapping and reconstructing a CFM image to become a three dimensional volume data [see column 1 lines 37-45]; and further in the three dimensional volume data the same pixel position in a scanned cross section has temporally reception echoes [see column 1 lines 47-50].

Kanda et al don't specifically mention first and second transducers and detect three dimensional motion of an object.

However, Kanda et al teaches an array of transducers that comprises a plurality of piezoelectric elements [see column 4 lines 50-55] to transmit waves onto the regions and acquire or producing two dimensional cross section images [see column 2 lines 1-9]. One skilled in the art would have known that an array of transducers made of first, second and n transducers. So an artisan can pick two transducers and designate them as first and/or second transducer (emphasis added).

Alternatively, Robinson also teaches one or two transducer array [see 0008] that can be used as first and/or second transducer array (emphasis added).

With regards to three dimensional motion of object, Schwartz et al teach three dimensional presentation of the motion or fluid flow [see column 6 lines 27-40]. Schwartz et al use Doppler power which is well known in the art to detect/measure velocity flow (emphasis added).

Schwartz et al further teach transducer elements to alternately scan the object [see column 3 lines 1-6] that can allow them to cross over each other (emphasis added).

Hossack teaches reconstructing and displaying multiple 2D into 3D of velocity flow [see column 8 lines 15-28].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Kanda et al and Schwartz et al references by Schwartz et al by detecting and displaying three dimensional motion of an object within an estimation region because Schwartz et al have discovered that utilizing power Doppler information alone in a three dimensional display eliminates the substantial clutter contribution of the structural information signals, eliminates pulsatility variation, provides excellent sensitivity to low energy flow signals, reduces Doppler angle effects, and provides a segmentation of the flow or motion characteristics in the three dimensional image [see column 2 lines 24-37, Schwartz et al]

Regarding claim 4, all other limitations are taught as set forth by the above combination.

Kanda et al teach a clutter component occurring due to reflection of signals from an organ [see column 3 lines 55-60].

Kanda et al don't specifically teach a contour component of the object.

However, Schwartz et al teach estimating of the border of blood flow and vessel wall [see figs 6d and column 6 lines 60-65].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Kanda et al and Schwartz et al by using the border of the object; for the purpose of providing a procedure with great accuracy.

Regarding claim 5, all other limitations are taught as set forth by the above combination.

Kanda et al don't specifically mention estimating partial motions of the object.

However, Robinson et al teach one or more identified regions of interest within a synthetic focused ultrasound image may be processed differently from other regions of the image to highlight or better define particular motional characteristics within the regions of interest, such as turbulent flow or different velocities of flow or motion [see abstract].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Kanda et al and Robinson references; to better define particular motional characteristics within the regions of interest.

Regarding claim 6, all other limitations are taught as set forth by the above combination.

Kanda et al don't specifically mention correlating of a plurality of one dimensional signal of the reflected signals.

However, Robinson teaches one dimensional array [see 0008, 0039] that could be incorporated into Kanda et al by one skilled in the art (emphasis added).

Therefore, one with ordinary skill in the art at the time the invention was made would have known to use an array of transducer in one dimension to obtain a plurality of one dimensional signal as suggested by Robinson; because acquire signals in one dimension is useful especially when obtaining translational motion of a moving target.

3. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanda et al (US Pat: 5,910,118) in view of Schwartz et al (US Pat: 5,474,073) and further in view of Robinson (Pub. No.: US 2004/0068188) as applied to claim 1 above and further in view of Shaulov (US Pat: 4,671,293).

Regarding claims 2-3, all other limitations are taught as set forth by the above combination.

Kanda et al don't explicitly mention biplane image including two scanning surfaces.

However, Kanda et al teach sequential transmission which means that if two transducers are used; they are transmitting or scanning alternately and therefore would

provide or acquire biplane image (emphasis added). One surface can be tissue of organ and another one could blood and they may not be in parallel to each other (emphasis added).

Alternatively, Shaulov teaches a biplane phased array ultrasonic transducer arrangement having effectively two arrays of ultrasonic oscillators and electrode patterns on opposite major faces of a piezoelectric material, each array consisting of several acoustically separated transducer elements which are electrically controlled to operate independently. The biplane phased array permits the real time imaging of two planar sectors which can be at any relative angle to another [see column 1 lines 8-15].

Therefore, one with ordinary skill in the art would have been motivated to combine the Kanda et al and Shaulov references; by using the biplane phased array ultrasonic transducer as taught by Shaulov because biplane phased array is especially useful in cardiac scanning. Simultaneous horizontal and vertical cross sections of the heart will allow the physician to evaluate more effectively the functioning of the heart and for the purpose of producing a dynamic image of a bodily function.

4. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanda et al (US Pat: 5,910,118) in view of Schwartz et al (US Pat: 5,474,073) and further in view of Robinson (Pub. No.: US 2004/0068188) as applied to claim 1 above and further in view of Coleman et al (US Pat: 4,932,414)

Regarding claims 9-10, all other limitations are taught as set forth by the above combination.



Kanda et al don't teach an ultrasonic therapeutic device.

However, Coleman et al teaches in accordance with this invention, a system is provided that integrates a rapid scan, real-time diagnostic ultrasonic system with a therapeutic ultrasonic system. The real-time diagnostic portion of the system provides three- dimensional and/or cross-sectional images of the tissue under scrutiny in real-time [see column 3 lines 2-7].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Kanda and Coleman references by using the therapeutic transducer assembly and the diagnostic transducer and the teaching of a display format that superimpose on a B-mode image [see column 3 lines 62-64] as taught by Coleman; for the purpose of better diagnosing the region of interest to provide an accurate evaluation as to prescribe the best possible treatment.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Applicant points out [see REM, column 13] that Kanda et al treat echoes reflected from organs as noise and eliminate them.

Examiner disagrees because Kanda et al disclose that even if tissues is in motion due to the heart beat, breathing; clutter components reflected from such tissues are removed [see column 14 lines 40-45]. Kanda et al do not consider tissues as clutter

and remove them; however, Kanda et al consider the motion as clutter and remove them but not the tissues or the organs (emphasis added).

Applicant also argues that Kanda et al fail to detect velocity component of 3D motion.

However, Schwartz et al teach three dimensional presentation of the motion or fluid flow [see column 6 lines 27-40]. Schwartz et al use Doppler power which is well known in the art to detect/measure velocity flow (emphasis added).

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Kanda et al and Schwartz et al references by Schwartz et al by detecting and displaying three dimensional motion of an object within an estimation region because Schwartz et al have discovered that utilizing power Doppler information alone in a three dimensional display eliminates the substantial clutter contribution of the structural information signals, eliminates pulsatility variation, provides excellent sensitivity to low energy flow signals, reduces Doppler angle effects, and provides a segmentation of the flow or motion characteristics in the three dimensional image [see column 2 lines 24-37, Schwartz et al]

Applicant argues that Coleman doesn't teach detecting velocity of 3D motion.

Coleman's reference is not relied on for detecting velocity of 3D motion.

Coleman's reference is relied on for the use of diagnostic and therapeutic teaching (emphasis added) and The invention combines two components, a real-time ultrasonic piezoelectric diagnosis unit and a high intensity, focused therapeutic ultrasonic sub-system [see column 1 lines 9- 16]. Coleman et al teaches a display

format of the therapeutic beam superimposed on a B-mode image [see column 3 lines 62-64 and fig 4].

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768